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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 20040122

Application Number: 09/267,199
Filing Date: March 12, 1999
Appellant(s): BHAT ET AL.

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Thomas Holsten
Holly Logue Prutz
David R. Marsh
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/17/2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 10-18, 20-22 and 25 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim 10-18, 20-22 and 25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this nucleic acid molecule subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed nucleic acid molecule subject matter.

The claims are drawn to isolated nucleic acid molecules comprising a nucleic acid sequence, or its complement, which hybridizes under specific conditions to SEQ ID NO: 100, 147, 153, 180, 199, or 232. The claims are also directed to isolated nucleic acid molecules comprising or consisting of SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232.

General uses of polynucleotides set forth in the specification, as filed, include acquiring genes, identifying polymorphisms, determining plant traits, measurement of proteins levels, modification of protein expression, and DNA mapping. (See at least

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pages 70-73.) None of these is considered to be specific and substantial in view of the limited information provided in the specification. No particular plant traits are attributed to any of SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232. No complete gene is disclosed for any of SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232, nor is a protein identified wherein expression levels, etc. are affected by any of SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232. No DNA maps or chromosomal locations are identified. No polymorphisms are identified. The specification does not disclose how a polymorphism would be recognized by those of ordinary skill in the art given the incomplete sequence disclosed.

The specification asserts on page 1 that the inventive nucleic acids encode tocopherol synthesis pathway enzymes. Each nucleic acid molecule claimed has at least one (in most cases, several) ATG "codons". However, it is not known for ANY of the claimed sequences what the ORF is, therefore it is unknown whether any sequence is actually translated into a peptide, or, if translated, what the activity or function of that peptide may be.

The claimed sequences range in size from 182-331 nucleotides in length, and all comprise several putative start codons. For example, SEQ ID NO: 100 is 261 nucleotides in length and comprises at least 5 putative start (ATG) codons. The specification fails to identify which, if any, of the several putative start codons is the start of an open reading frame for any nucleic acid molecule, or whether there is a stop codon in frame with any putative start codon. Pages 239-242 of the specification discloses that putative peptides encoded by the claimed nucleic acid sequences share some degree of homology to a proteins found in the NCBI database, but there is no disclosure or evidence anywhere that that peptides putatively encoded have any

activity, specifically enzymatic activity, or would be expected to have enzyme activity (e.g. based on comparison of tertiary structures, active regions, conserved domains, etc.) One of ordinary skill in the art would have reason to doubt that any of SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232 is one which comprises a full length ORF and/or expresses a functional protein based upon the short length of the claimed SEQ ID NO's. It is possible that one or more of the claimed sequences encodes a fragment of an enzyme; however, it is not disclosed whether that fragment so encoded has activity or another function such that that the fragment has utility under 35 USC 101.

Further research and experimentation would be required to identify a full length sequence that encoded a full-length protein, to characterize the chromosomal location, to determine the presence of polymorphisms, and to determine any associated plant traits or protein expressed by any of SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232. Identifying and studying the properties of the claimed subject matter itself or the mechanisms in which the claimed subject matter is involved does not define a "real world" context or use.

These uses require that the claimed nucleic acid molecule be usable as a laboratory reagent. Laboratory reagents must be sufficiently characterized and their properties understood to be used in these types of methods. In the absence of such characterization, no meaningful information is provided. The claimed nucleic acid molecules are starting materials for further research and not research tools.

Claims 10-18, 20-22 and 25 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific, and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 10-18 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a lack of written description rejection.

Claims 10-18 and 20-22 are directed to a nucleic acid molecule comprising SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232. The use of the term "comprising" is interpreted to encompass genomic sequences/clones; no full-length gene or ORF has been disclosed by the instant specification. As genomic sequences may comprise introns and noncoding regions, regulatory regions, etc., one skilled in the art would not be able to readily envision members of the genus embodied by the claim, therefore claims 10-18 and 20-22 are rejected.

(11) Response to Argument

Appellant's arguments are addressed *seriatim*.

Sections 8A, 8B and 8C

Appellants assert that the claimed invention meets the utility and enablement requirements because they have disclosed nucleic acid molecules which "provide identifiable benefits, for example, use to identify the presence or absence of a polymorphism, as a hybridization probe for expression profiling, and use to modulate tocopherol enzyme levels in plant cells." The examiner does not agree that the nucleic acid molecules provide any specific benefit to the public in their current form but rather require further experimentation to determine whether such a benefit can be found.

Appellants also assert that the specification has provided an adequate description for nucleic acid molecules "comprising" SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, and 232 because they have disclosed each of SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, and 232. The examiner does not agree that the structure of SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, and 232 provides adequate description for claims encompassing the nucleic acid for a genomic sequence. Neither the structural and functional properties of any gene (including introns and other non-coding

sequence) comprising SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232 are disclosed in the specification.

The Examiner agrees that the “The threshold of utility is not high: An invention is ‘useful’ under section 101 if it is capable of providing some identifiable benefit,” with the proviso that the benefit be “identifiable” in the original disclosure either as a specific assertion or being readily apparent from the disclosure (i.e. well established). The Examiner also agrees “the invention must have specific, i.e. not vague or unknown benefit” and “must provide a real world, i.e. practical or substantial, benefit.” Whether the instant application has met this burden is the subject of this appeal.

It is noted that the brief states in footnote 2 on page 6 that it “is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicants are not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.” The latter part of the footnote appear to contradict appellant’s assertion on page 10 of the Brief that “nucleic acid molecules of the present invention comprise sequences that encode enzymes...” It is further noted that the brief does not dispute that no open reading frame (ORF) nor any biological activity for any encoded protein has been disclosed for SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232. Appellant argues that as the claims are directed to nucleic acid molecules which encode enzymes “or fragments” thereof, a complete ORF or start codon is not necessary to use the claimed nucleic acid molecules as probes, to detect the presence of absence of polymorphisms, or in expression studies.

Appellant argues that the claimed nucleic acid molecules can be used to detect the presence and/or identity of polymorphisms, as hybridization probes for expression profiling or to isolate other nucleic acids, or to initiate a chromosome walk, and in genetic mapping. The Examiner maintains that further research is required for such uses.

A use to as a hybridization probe or to purify other nucleic acids requires further experimentation to determined the utility or the nucleic acid molecules identified or purified. MPEP 2107 states, "An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring." The instant specification sets forth no such correlation for any nucleic acid molecule with any condition. It is noted that this section of the MPEP goes on to state that:

On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

- (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
- (B) A method of treating an unspecified disease or condition;
- (C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
- (D) A method of making a material that itself has no specific, substantial, and credible utility; and

(E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

All of these situations more closely match appellant's disclosed uses. They do not define substantial utilities.

Footnote 3 on page 6 of the brief states discusses uses of microarrays.

Appellant is not claiming microarrays or collections of nucleotides and the specification does not associate any of the claimed sequences with any trait of interest. Contrary to appellant's assertions, further experimentation is required to identify a "real world use." A negative result to such a screen tells what the nucleic acid is not and cannot be used for. A positive result to such a screen requires further experimentation to determine what, if anything, such a change means. It is not an immediate benefit except in the sense to indicate that further research might yield a "real world use."

The brief on page 7 discusses gas chromatographs. MPEP 2107 in discussing research tools sets forth the following:

Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is inventions to be used in a research or laboratory setting. Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact "useful" in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as "research tool," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific and substantial utility for the invention.

Again, further experimentation is required to use determine and confirm any of the uses set forth by appellant for the claimed nucleotide sequences.

The gas chromatograph example set forth by appellant, particularly as discussed in Footnote 6 on page 8, is not analogous to the present disclosure. A gas chromatograph is a piece of equipment designed and built for a particular use. Such equipment is fully tested, evaluated, and calibrated to ensure accurate results. Those skilled in the art use gas chromatographs to analyze both known and unknown compounds. When the compound is unknown, the results obtained are compared to results for known compounds, e.g. standards. Appellants did not design the claimed nucleotide sequences for any particular purpose. They merely isolated them. They have not tested, evaluated, or calibrated the claimed nucleotide sequences for any particular use. Sampling for the presence or absence of chlorine in a crude oil sample is not analogous to the present situation. The presence or absence of chlorine in a crude oil sample has a known meaning based upon prior research. Absent establishment of this association between presence of chlorine and destruction of catalyst, the presence or absence of chlorine in a sample would not provide any useful information to the refinery manager. Likewise, the presence or absence of any of the claimed nucleotide sequences in a sample (or polymorphisms thereof) has no meaning absent some association. Further experimentation is required to determine what that meaning or association might be.

In addition, this gas chromatograph analogy fails address Appellants' own definition of the term polymorphism. The specification (page 85, lines 11-13) defines

“polymorphism” as “a variation or difference in the sequence of the gene or its flanking regions that arises in some members of a species.” It follows from this definition that if there is no “variation or difference in the sequence of the gene or its flanking regions” among “members of a species,” then no polymorphism exists, i.e. a polymorphism is absent, in this region of the genome. A “polymorphism” is a collective concept defined by at least two variants (or alleles) found within members of a species collectively.

Thus, one detects the *presence* of a polymorphism by analyzing multiple members of the species, i.e. analyzing a population. While one can detect the absence (or presence) of a specific allele of the polymorphism in a specific individual member of the species, one cannot detect the *absence* of a polymorphism *per se* based on one individual alone. The absence of a particular allele necessarily means that a different allele is present. The specification fails to disclose a specific and substantial utility for the claimed invention in the capacity of detecting polymorphisms, because it does not disclose whether the claimed nucleic acid molecule can, in fact, be used to detect any polymorphism whatsoever. The specification does not disclose that any of SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232 is known to comprise or be associated with any polymorphism. Thus, the specification leaves open the possibility that there may be no polymorphism to detect. With respect to the gas chromatograph analogy, one can only detect the absence of a compound, such as chlorine, in a sample, *if* it was already known that chlorine could, in fact, be detected by the gas chromatograph were it present in the sample.

The specification generally teaches using the claimed polynucleotides to identify a polymorphism, but fails to teach that a polymorphism could in fact be detected, or a specific polymorphism that could be detected. The specification generally teaches using a polymorphism, detectable with the claimed nucleic acid molecule, as a molecular marker for a linked trait of interest, but fails to teach either the polymorphism or the trait of interest. The court in *In re Kirk and Petrow* (153 USPQ at 53) held:

We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.

The specification (page 85, lines 11-13) defines "polymorphism" as "a variation or difference in the sequence of the gene or its flanking regions that arises in some members of a species" (emphasis added). The following pages of the specification discuss various types of sequence polymorphisms and how they are detected. It is noted that on page 88, line 23, the specification states, "By correlating the presence or absence of it [a polymorphism] in a plant with the presence or absence of a phenotype..." Thus, the specification acknowledges that further analysis is required to determine a use for a polymorphism even assuming one is found. A change of

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phenotype and correlation with phenotype must be found; linkage analysis must be performed.

Even to determine whether a polymorphism exists at a specific chromosomal location requires hybridization to at least two individual chromosomes, and generally involves analyzing genomic DNA from multiple members of a species; the specification discloses no such analysis. The specification fails to disclose: 1) whether the claimed nucleic acid molecule can in fact detect a polymorphism, or even whether such a polymorphism exists; and 2) at least one specific example of at least one of the types of polymorphisms described in the specification. The specification does not disclose any utility in this context for a nucleic acid molecule or EST that can NOT detect a polymorphism. Therefore, using the claimed invention to first determine whether or not the claimed nucleic acid molecule can, in fact, detect a polymorphism *is* to determine whether or not the claimed invention has a utility that requires detecting a polymorphism, i.e. it is “use testing” and not substantial. Since the specification fails to identify even one specific polymorphism that can be detected with the claimed nucleic acid molecule, the specification fails to show any specific correspondence between the disclosed general utility and the claimed subject matter, regardless of any specific application requiring detection of polymorphisms. Thus, as in *In re Zeigler* (26 USPQ2d 1603), the purported (asserted) utility does not provide an actual benefit to the public because further research is needed.

Appellants argue that the claimed nucleic acid molecules have utility as “probes for other molecules or as a source of primers”; in particular, to use the claimed nucleic acid molecules to identify nucleic acid molecules encoding enzymes in the tocopherol pathway, or to initiate a chromosome walk. The argument in the brief compares the claimed invention to a microscope.

A microscope is useful for determining structure of *any* sample of interest at the macroscopic, microscopic or molecular level, depending on the type of microscope. It is a generally useful tool for a wide range of specific uses. One does not usually use a microscope to study related microscopes. In contrast, Appellant argues that the claimed nucleic acid molecules are useful to detect or measure nucleic acid molecules that possess a certain level of structural relatedness to the claimed nucleic acid molecules, the level of relatedness being defined by hybridization to the claimed nucleic acid molecules. However, the specification discloses *no* nucleic acid molecule that hybridizes with the claimed nucleic acid molecules that does *not* consist or comprise SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232 or its complement. In order for hybridization between two nucleic acid molecules to occur, they must share at least some nucleotide sequence that is fully complementary. The length of fully complementary sequence required to detect hybridization depends primarily on the stringency of the specific hybridization conditions employed, the lower the stringency the shorter the length of fully complementary sequence required. The specification also fails to disclose any hybridization conditions required for detecting nucleic acid molecules that do *not* contain the nucleotide sequence of any of SEQ ID NO: 1, 100,

147, 153, 158, 161, 180, 184, 199, or 232 or its complement, and fails to disclose any source for such a nucleic acid molecule.

All arguments pertaining to the utility of the claimed invention with respect to studying the corresponding genomic DNA and mRNA found in soybean or corn, would also apply to any homologous nucleic acid molecules found in other plant species. In so much as the specification fails to describe a specific and substantial utility for the corresponding nucleic acid in soybean or corn, so does it fail to describe a specific and substantial utility for the corresponding nucleic acids in other plant species.

Appellants cite *Carl Zeiss Stiftung v. Renishaw PLC* in support of their position that utility has been established. However, this decision is with respect to a mechanical device and not a laboratory reagent or research tool. Furthermore, applicant mischaracterizes the findings in this decision. This decision concerned claim interpretation and the CAFC found that the district court had erred in their interpretation of what the claim embraced and thus what was required to establish utility. The claimed device was found to fulfill the stated objective of mounting a stylus by the CAFC. These facts do not correspond to the instant specification

While the specification teaches (page 42, lines 12-14) that the claimed nucleic acid molecule “*may be employed to obtain other nucleic acid molecules*” (emphasis added),; e.g. those which encode tocopherol pathway enzymes, the specification does not indicate that any such nucleic acid molecules *had been* obtained, nor does it describe any characteristics possessed by such nucleic acid molecules. As to whether such molecules could, in fact, be obtained, the Office can neither prove nor disprove the

assertion because the Office does not have laboratory facilities. At the time the application had been filed, future experimentation on the part of one skilled in the art would have been required to determine which, if any, other plant species contained nucleic acid molecules that could have been obtained using the claimed invention, and under what experimental conditions.

With respect to using the claimed nucleic acid molecule to initiate a chromosome walk, such as to isolate a promoter of the corresponding gene, the specification fails to disclose any characteristics of the corresponding promoter, or any other promoter within "chromosome walking" distance; neither structural characteristics, by which the promoter might be identified, nor functional characteristics, by which a specific and substantial use for the promoter might be determined.

In this context, the claimed invention does not compare to a golf club, because one knows what a golf ball is and how to use the golf club to hit it, whereas the specification does not disclose or describe with particularity any known useful nucleic acid molecule that can be obtained, such as the corresponding promoter - it simply invites the skilled artisan to provide such information by further experimentation.

Even assuming *arguendo* that the corresponding promoter exists is no more guidance for its isolation, and eventual use, than knowing that a haystack contains a needle - at least one is presumed to know what the needle looks like. Also, the specification does not disclose the distance or direction one has to walk on a chromosome from the corresponding location to reach the corresponding promoter. Thus, starting the walk at the corresponding chromosomal location is no more help in

identifying the promoter than is picking a specific location in a haystack to start looking for a needle when one does not know where the needle is relative to the starting location. Initiation of a chromosome walk at the corresponding chromosomal location is considered non-specific because any EST would serve the purpose for isolating an uncharacterized promoter, since any chromosomal location is expected to be linked to a promoter. The specification fails to disclose sufficient characteristics of the corresponding promoter, such as its sequence or precise location relative to the genomic location corresponding to the claimed nucleic acid molecule, to inform one of what the corresponding promoter is or when it has been isolated. For example, a nucleotide sequence is identified during the chromosome walk as a putative promoter by sequence analysis, is then subcloned into operable linkage with a reporter gene and transfected into an appropriate cell, but found not to express the reporter gene in the cells. This result could mean the putative promoter: is not truly a promoter, i.e. a false positive; is not the corresponding promoter; or is incomplete, i.e. lacked additional sequence elements required for promoter activity in the cotton boll cells. Substantial utility means that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate* benefit to the public," *Nelson v. Bowler*, 206 USPQ2d 881, 883 (CCPA 1980) (emphasis added). Since the specification does not describe the corresponding promoter, or any other specific nucleic acid molecule, sufficient to inform one skilled in the art that it has been isolated, there can be no "*immediate* benefit to the public" in using the claimed nucleic acid molecule in this capacity; "a patent is not a

hunting license. It is not a reward for the search, but compensation for its successful conclusion,” *Brenner* at page 696.

With respect to the “real world” value of ESTs in general (Brief, page 13), it is asserted that there is “no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed ‘real world’ value to such nucleic acid molecules.” It is unclear as to what evidence Appellants are alluding. The evidence supplied by Appellants shows that a multimillion dollar industry has arisen surrounding buying and selling EST databases and clones, not that anyone in this industry has bought or sold the claimed subject matter. It is noted that simply because a product, such as an EST sequence database or clone library, is bought and sold does not mean it has patentable utility.

With respect to credibility, appellant is reminded that in order to meet the requirements of 35 USC 101, the specification must disclose at least one utility that is specific and substantial, as well as credible (absent a showing of well established utility, which would presume that the utility was credible). The claims have been rejected because 1) the specification fails to disclose at least one utility that is both specific and substantial, and 2) no convincing evidence has been presented to show that an EST, for which only its nucleotide sequence and source have been disclosed, has a well established utility.

The brief does not appear to directly argue for a well established utility for the claimed invention; however, the arguments concerning the commercial value of ESTs in general (Brief, page 13) may implicitly be directed to a well established utility for any

EST in general, and the claimed nucleic acid molecules in particular. However, such evidence is not relevant to 35 USC 101.

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The Examiner maintains that the uses asserted for the claimed invention are methods where the claimed invention is, itself, an object of scientific study, e.g. to determine whether the corresponding genomic DNA of corn or soybean plants contains a polymorphism that can be detected with the claimed invention. The specification cannot enable or tell how to use the invention within 35 U.S.C. 112, first paragraph, if there is no patentable utility within 35 U.S.C. 101. The Examiner maintains that there is no patentable utility for the claimed invention for the reasons set forth above and thus the claims are not enabled.

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The issue is whether Applicant was in possession of the genus being claimed. This genus is not restricted to any particular disclosed subgenus or species, such as vectors comprising any of SEQ ID NO's 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232. The only nucleic acid molecule described by complete structure is that consisting of SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232. The only nucleic acid molecules comprising SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232 described in the specification by other characteristics are generic vectors comprising SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232. While it is

acknowledged that Appellant need not describe “every nuance” of the claimed invention, the written description must bear a reasonable correlation to that which is claimed. The disclosed subgenus and species embraced by the claims are not representative of the entire genus being claimed. The genus of nucleic acid molecules being claimed embraces any and every type of nucleic acid molecule that comprises SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232 and additional sequences of any size and sequence, including genomic DNA, not just vector backbones. Clearly, at the time of filing, Appellant was not in possession of genomic materials that contain the common EST fragment, which are embraced by the open-ended claims. The specification does not disclose what characteristics these additional sequences may or may not have that are consistent with the operability of the nucleic acid molecules as probes or primers for detection of SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232 in a target sequence, and all disclosed uses for the claimed nucleic acid molecules are fundamentally as probes or primers, at least in some aspect. The specification does not disclose encoding sequences or open reading frames (ORFs).

With respect to full length mRNAs, cDNAs and genomic sequences, one skilled in the art would reasonably conclude that the claims embrace these nucleic acid molecules, and the specification provides no physical (i.e. structural) characteristics of these molecules to distinguish them from other nucleic acid molecules comprising SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232 and no other indication that would suggest Appellant possessed them. This particular subgenus embraced by the

claims has a disclosed potential utility not possessed by those members of the claimed genus useful only in hybridization. Full length mRNAs, cDNAs and genomic sequences (genes) would encode the corresponding protein.

A fundamental issue here is specific to the very narrow class of product that is nucleic acid molecules. The basic question upon which Appellants and the Examiner disagree is whether the disclosure of a partial sequence of otherwise uncharacterized nucleic acid molecules that may encode a corresponding protein is sufficient to establish possession of a broad genus based solely on the description of the partial sequence, where the broad genus embraces the uncharacterized nucleic acid molecules by default. The subgenus of uncharacterized nucleic acid molecules that encode any corresponding protein is explicitly alluded to in the specification, and disclosed as possessing an additional use *not* possessed by any other members of the broad genus being claimed, i.e. encoding the protein. The specification fails to provide any structural or functional characteristic for these desired nucleic acid molecules, which encode the protein, that would distinguish them from the other members of the genus, which simply comprises SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232 as the sole distinguishing feature.

In the instant case, the only species specifically enumerated is the nucleic acid molecule of one of SEQ ID NO: 1, 100, 147, 153, 158, 161, 180, 184, 199, or 232, itself. The specification does not show one skilled in the art that any other sequences

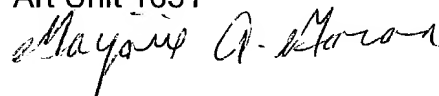
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(e.g. longer genomic sequences, specific coding regions, etc.) or subcombinations were possessed by Appellant, and thus the embracing genus was also not possessed.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,


Marjorie A. Moran
Primary Examiner
Art Unit 1631




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January 22, 2004

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